



Edwards

**URGENT – FIELD SAFETY NOTICE**  
**Edwards Lifesciences Expandable Introducer Sheath Set**  
**Model Number: 9610ES14**  
**Lot number: 59390915**  
**Ref: FCA-24**

Date:

**Attention: For distribution to Risk Management & Users of the Expandable Introducer Sheath Set**

**Details on affected devices:**

*14F Edwards Expandable Introducer Sheath Set, Model number 9610ES14, Lot number 59390915, intended for use with the 23mm and 26mm SAPIEN 3 Commander Delivery System in the clinical investigation, Study #2012-07, Safety and Performance Study of the Edwards SAPIEN 3 Transcatheter Heart Valve*

**Description of the issue:**

Edwards has identified during internal testing that in some cases the 14F ESheath shaft may not expand as intended causing tearing at the liner. If this were to occur clinically, the torn liner creates a potentially rougher surface which may cause or contribute to a vascular complication during removal of the device from the patient.

Edwards has therefore decided to recall the above lot of the 14F expandable Introducer Sheath set.

This Field Safety Notice does not pertain to the valve implant and patients already implanted are not affected by this Field Safety Notice.

**Action requested:**

1. Our records show that you have received the affected Expandable Introducer Sheath Set of lot 59390915. These devices should not be used. Please review and quarantine any affected inventory immediately. Please return all unused affected product from your inventory to Edwards.

An acknowledgment form is included to assist you in the review of your inventory. Once you have verified your inventory, please complete the attached acknowledgment form (even if you have no inventory) and fax it back to Pascal Lehmann at +41 22 787 4303 within three days of receipt of this Field Safety Notice. This is to confirm that you have reviewed this notice and have taken appropriate action.

**Edwards Lifesciences Services GmbH**

Edisonstraße 6 · 85716 Unterschleißheim · Germany · Telefon (0 89) 9 54 75-0 · Telefax (0 89) 9 54 75-400  
Bankverbindung: Deutsche Bank, München (BLZ 700 700 10) Konto-Nr. 1 990 068  
Geschäftsführer: Dieter Fellner, Jean-Francois Beyrath · Sitz: Unterschleißheim · Registergericht München HRB 128727



Edwards

Please contact Pascal Lehmann (+41 22 787 4447 or pascal\_lehmann@edwards.com) to obtain a Returned Goods Authorization number and replacement product.

Please return all affected product to the following address,

Edwards Lifesciences AG  
Altsagenstrasse14 CH 6048  
Horw LU, Switzerland  
Phone 41.41.348.2121

2. The 16F Expandable Introducer Sheath Set, Model 916ES23 may be considered for use in place of the 14F Expandable Introducer Sheath Set, Model 9610ES14. The 16F device expands to a maximal diameter of 7.9mm when the 26mm Commander is passed through it. In comparison, the 14F device expands to a maximal diameter of 8.0mm. Hence, the use of the 16F Expandable Introducer Sheath Set rather than the 14F does not impact the risk associated with the transfemoral access approach.

**Transmission of this Field Safety Notice:**

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

We sincerely regret the inconvenience caused by this action and greatly appreciate your immediate attention to this matter. If you have any questions that have not been answered by this letter, please contact your Edwards representative.

Sincerely,

Karin Fricke  
Regional Manager Regulatory Affairs Europe

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

**Edwards Lifesciences Services GmbH**

Edisonstraße 6 · 85716 Unterschleißheim · Germany · Telefon (0 89) 9 54 75-0 · Telefax (0 89) 9 54 75-400  
Bankverbindung: Deutsche Bank, München (BLZ 700 700 10) Konto-Nr. 1 990 068  
Geschäftsführer: Dieter Fellner, Jean-Francois Beyrath · Sitz: Unterschleißheim · Registergericht München HRB 128727



Edwards

**URGENT – FIELD SAFETY NOTICE**  
**Edwards Lifesciences Expandable Introducer Sheath Set**  
**Model Number: 9610ES14**  
**Lot number: 59390915**  
**Ref: FCA-24**

**Acknowledgment Form**

«CENTRE»  
«CONTACT\_NAME»  
«DEPARTMENT»  
«ADRESSE»  
«CITY», «STATE» «ZIP\_CODE»

We acknowledge receipt of this Field Safety Notice involving the Edwards Lifesciences Expandable Introducer Sheath Set Model Number: 9610ES14, Lot number: 59390915 We have reviewed and understand the information contained within and have taken the appropriate actions and disseminated this information to any affected staff, services and/or facilities.

**PLEASE SEND COMPLETED SIGNED FORM TO Pascal Lehmann at  
+41 22 787 4303**

**Note: Please indicate "NONE" if you have no Custom Kit inventory to return.**

<u>Product Code / Model</u>	<u>Lot Number</u>	<u>Quantity Shipped From EW</u>	<u>UOM</u>	<u>Order Number</u>	<u>Date Shipped from EW</u>	<u>Number of units to be returned</u>	<u>Number of units used or discarded</u>	<u>RGA Number</u>

Name (Print): \_\_\_\_\_

Signature: \_\_\_\_\_

Title and Department: \_\_\_\_\_

Contact Info.: / Tel. No. / Fax No. / Email: \_\_\_\_\_

Date: \_\_\_\_\_